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The biocompatibility of dense and porous Nickel–Titanium produced by selective laser melting

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ABSTRACT

Nickel–Titanium shape memory alloys (NiTi-SMA) are of biomedical interest due to their unusual range of pure elastic deformability and their elastic modulus, which is closer to that of bone than any other metallic or ceramic material. Newly developed porous NiTi, produced by Selective Laser Melting (SLM), is currently under investigation as a potential carrier material for human mesenchymal stem cells (hMSC). SLM enables the production of highly complex and tailor-made implants for patients on the basis of CT data. Such implants could be used for the reconstruction of the skull, face, or pelvis. hMSC are a promising cell type for regenerative medicine and tissue engineering due to their ability to support the regeneration of critical size bone defects. Loading porous SLM-NiTi implants with autologous hMSC may enhance bone growth and healing for critical bone defects. The purpose of this study was to assess whether porous SLM-NiTi is a suitable carrier for hMSC. Specimens of varying porosity and surface structure were fabricated via SLM. hMSC were cultured for 8 days on NiTi specimens, and cell viability was analyzed using two-color fluorescence staining. Viable cells were detected on all specimens after 8 days of cell culture. Cell morphology and surface topography were analyzed by scanning electron microscopy (SEM). Cell morphology and surface topology were dependent on the orientation of the specimens during SLM production. The Nickel ion release can be reduced significantly by aligned laser processing conditions. The presented results clearly attest that both dense SLM-NiTi and porous SLM-NiTi are suitable carriers for hMSC. Nevertheless, before carrying out in vivo studies, some work on optimization of the manufacturing process and post-processing is required.

1. Introduction

Nickel–Titanium shape memory alloys (NiTi-SMA) exhibit mechanical and chemical properties which make them attractive candidate materials for various types of biomedical applications (e.g., stents, shape memory staples for compression osteosynthesis, interbody fusion devices, hip endoprosthesis and acetabular cups with integrated self-expanding NiTi elements) [1]. These alloys demonstrate good deformability that is associated with their pseudoelastic behavior. A mechanically imposed strain as high as 8% can be reversibly recovered after unloading. This provides a damage tolerance which is not demonstrated by other metals or ceramics. Most importantly, porous NiTi-SMA exhibits an elastic modulus (28 GPa) closer to that of bone (0.3–20 GPa) than any other metallic or ceramic material [2]. Metals commonly used for orthopedic implants have a Young's modulus in the range of 100 to 200 GPa (~110 GPa for Titanium, ~190 GPa for austenitic stainless steel, and ~193 GPa for Co-based alloys) [2,3]. This large difference in stiffness between implant material and the surrounding human bone leads to an inhomogeneous stress distribution on the bone. This stress-shielding effect may cause bone resorption and weakens bone locally which results in aseptic implant loosening [3]. Due to its elastic modulus, NiTi-SMA may reduce the stress-shielding effect when used as an orthopedic implant material. It has been reported that implantation of NiTi-SMA as a weight bearing bone graft substitute led to osseointegration and a good bone–implant contact [4].

Nevertheless, the production of highly complex NiTi parts, which could be used as bone substitutes or implants, is challenging due to poor machinability of the alloy [5]. Several powder metallurgical processing technologies are suitable for the production of both dense and porous NiTi parts [6–8], but they often have limitations with respect to complexity. Generally, the production of single parts, e.g., individual implants, is challenging. In recent years, additive manufacturing (AM) has established promising methods for medical applications [9,10]. These laser assisted freeform fabrication methods provide special opportunities due to their use of the additive operation principle.

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By building up material by adding layers instead of removing material, they offer a nearly unlimited flexibility of the part's geometry and complexity. AM, therefore, has a high potential for the production of scaffolds, individual bone substitutes and implants [9,10]. While NiTi-SMA are gaining interest for both engineering applications and for medical applications, AM of NiTi has received less attention so far. To date, there are almost a dozen international research papers or conference proceedings concerning the processing of NiTi via AM techniques [11–20]. This paper reports on the fitness and biocompatibility of additive manufactured NiTi parts as implant material.

Only a few AM technologies are suitable for the production of load bearing metallic implants. One of those technologies is the Selective Laser Melting process (SLM). Fig. 1 shows several steps of the SLM-procedure. The starting point for this processing technique is a three-dimensional CAD model of the part (Fig. 1 A) which is sliced in horizontal layers of a defined thickness (Fig. 1 B). Each layer contains specific information regarding the geometry of the part. To fix the part on the substrate material and to enhance heat conduction during SLM processing, support structures are developed and added to the sliced CAD model (Fig. 1 B). These filigree support structures are built up from the same material and in the same SLM process as the desired part, but are removed mechanically afterwards. The SLM process is a series of repeats of the same procedure which applies powder layers and transfers the specific geometrical information of each layer into the material by melting the powder with a laser beam (Fig. 1 C). After solidification, a full metallurgical fusion between adjacent laser scan tracks (hatches) and layers yields the geometry of the part. Fig. 1 D exhibits a final NiTi structure which was realized by SLM. Further details on the SLM procedure in general and a detailed description of process parameters are reported elsewhere [18,21].

SLM enables the production of highly complex and tailor-made implants for patients on the basis of CT data. Such implants could be used for the reconstruction of the skull, face, pelvis, or vertebral body defects. For the reconstruction of critical size bone defects, precultivation of a scaffold with autologous mesenchymal stem cells can enhance osseointegration and lead to a stable bone implant contact [22]. Newly developed porous NiTi, produced by Selective Laser Melting (SLM-NiTi), is currently under investigation as a potential carrier material for human mesenchymal stem cells (hMSC).

hMSC can be differentiated in vitro into osteoblasts [23], chondrocytes [23], tenocytes [24] and adipocytes [23]. hMSC can be easily expanded in vitro and retain their developmental potential during extensive cultivation steps or cryopreservation [25]. It has been shown in animal models that the implantation of MSC supports the regeneration of critical sized bone defects [22]. For the treatment of local bone defects, expanded autologous hMSC may be applied when previously loaded on a porous SLM-NiTi carrier matrix. Osseointegration and wound healing may be improved. The scientific objective of the present work was to determine whether newly developed SLM-NiTi biomaterial is suitable for implants and a potential carrier for hMSC.

2. Materials and methods

2.1. Production of the specimens

The pre-alloyed powder used for these studies was initially produced by gas atomization (TLS Technik GmbH, Bitterfeld) of as-cast NiTi ingots (Fig. 2 A) with the following chemical composition: 49.7 at.% Nickel and 50.3 at.% Titanium. Details are previously described [18]. Due to the moderate cooling rate during gas atomization, the powder particles feature a spherical shape (Fig. 2 B). Particle size was ranged between $d_{10} = 45$ µm and $d_{90} = 110$ µm (Fig. 2 C).

The SLM process was performed by using a commercial SLM system (Realizer SLM 100; MTT Technologies GmbH, now SLM Solutions GmbH, Lübeck, Germany). This instrument is equipped with a continuous wave 100 W Ytterbium fiber laser (wavelength 1070–1080 nm, TEM_{00}). Generally, high temperature processing of NiTi is highly complex. Powder or ingot metallurgical processing methods for NiTi are usually associated with a significant increase in impurity levels due to the high reactivity of the melt [26–28]. The functional properties of the material are very sensitive to the impurity content and can be decreased due to pick up of impurity elements [26,27]. Hence, the SLM process was carried out in argon atmosphere in order to minimize oxidation. In a recent study, we showed that successful SLM processing of NiTi is accompanied by only a slight pickup of oxygen (30 ppm) [18]. We also showed that using high quality ingot raw material resulted in an impurity level of both oxygen and carbon of SLM-NiTi below the limits for medical NiTi (oxygen: 0.05 wt.%, carbon: 0.05 wt.%) prescribed in ASTM 2063-05.

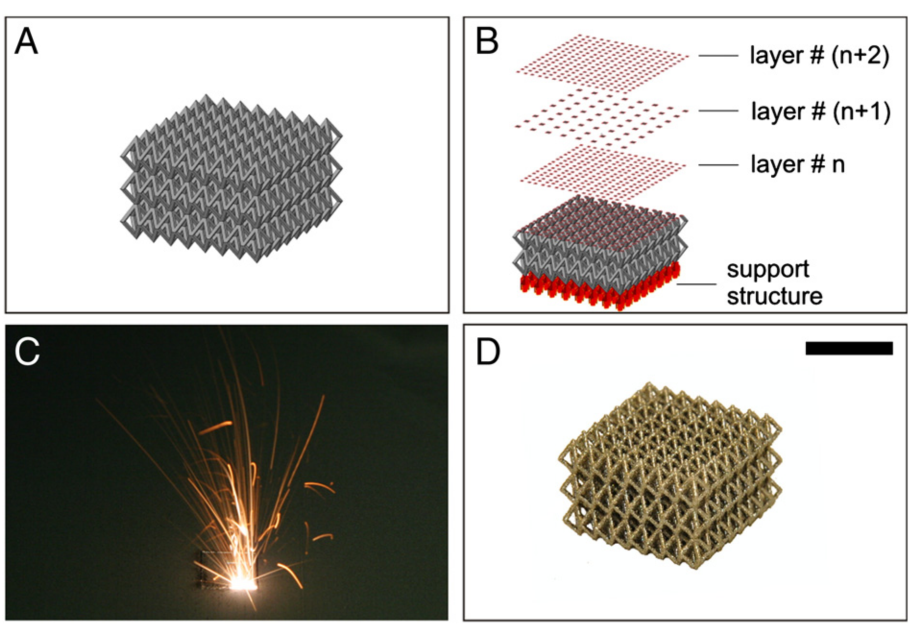

Fig 1. The SLM-procedure: CAD model of the later part (A); CAD model prepared for SLM (B); laser–material interaction during SLM (C); finished NiTi-SLM structure (D; scale bar = 10 mm).